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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/109,858 07/02/98 RAO

M T5530.CIP

HM12/0131

EXAMINER

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ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 01/31/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary	Application No.	Applicant(s)
	09/109,858	RAO ET AL.
	Examiner	Art Unit
	Janet Kerr	1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 11 September 2000.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 12,15,16,21,23,24,26-33,44 and 59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 12,15,16,21,23,24,26-33,44 and 59 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s). _____ .
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . 20) Other: _____ .

Continued Prosecution Application

The request filed on 11/6/00 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/109,858 is acceptable and a CPA has been established. An action on the CPA follows.

Applicants' amendment, filed 9/11/00, has been entered.

Claims 35, 37, 43, 45, and 49-58 have been canceled by this amendment.

Claims 12, 15, 16, 21, 23, 24, 26-33, 44, and 59 remain pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 59 remains rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 59 is directed to a method of isolating a pure population of mammalian CNS neuron-restricted precursor cells which requires a sample of mammalian embryonic stem cells. It has been argued that the claimed invention is enabled by the teachings in the specification, and further, that in view of the teachings of Thompson *et al.*, which demonstrate neuronal differentiation in human ES cells, one of skill in the art would know how to obtain ES cells for use in the instant invention. However, as stated in the previous office actions, the specification is not enabling for isolating a pure population of human CNS neuron-restricted precursor cells using human embryonic stem cells as a starting material. For a population of cells to be defined as embryonic stem cells, *per se*, establishment that the embryonic stem cells retain their

totipotential capacity and are able to generate cells of all lineages, including germline, after being introduced into a host blastocyst, is necessary. This has not been demonstrated either in the specification or in the reference of Thompson *et al.* Absent a showing of totipotency, and in view of the teachings in the art at the time of filing that establishing embryonic stem cells in species other than mice is neither routine nor predictable, the claimed invention is not commensurate in scope with the teachings in the specification and would require undue experimentation to practice the invention as claimed. Thus, in view of the lack of guidance in the specification with regard to the process of obtaining human embryonic stem cells, the use of the cells in the claimed cell culture method is not enabled.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12, 15, 16, 21, 23, 24, 26-33, 44, and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 12, 21, 26, and 27 are rendered vague and indefinite by the phrase "fail to proliferate or differentiate in astrocyte-promoting medium" as it is unclear if the neuron-restricted precursor cells fail to differentiate into CNS neuronal cells or if the neuron-restricted precursor cells fail to differentiate into a different cell type.

Claims 12, 21, 26, 27, and 59 are rendered vague and indefinite as the claims appear to be incomplete as written. The preamble of the claims require isolation of a pure population of cells, however, the last step recited in the method is incubation of a subpopulation of cells. At what step in the method are the pure population of neuron-restricted precursor cells isolated?

Claim 44 is rendered vague and indefinite for the following reasons: the phrase "derivatives thereof" is confusing because it is unclear what type of derivation of the neuron-restricted precursor cells are required; it is unclear what is meant by the phrase "neurological activity"; and it is unclear what type of reaction is monitored, and how the monitoring is practiced.

Claim Rejections - 35 USC § 102 and 103

In view of applicants arguments and the amended claims, the rejections under 35 USC 102(b) and 35 USC 103(a) have been withdrawn. The references cited do not teach nor make obvious the pure population of neuron-restricted precursor cells, methods of isolating the cells or methods of using the cells.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet M. Kerr whose telephone number is (703) 305-4055. Should the examiner be unavailable, inquiries should be directed to Deborah Clark, Supervisory Primary Examiner of Art Unit 1633, at (703) 305-4051. Any administrative or procedural questions should be directed to Kimberly Davis, Patent Analyst, at (703) 305-3015. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-7401.


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